

H.pylori

RAPID TEST



*Rapid test for the qualitative detection of **H. pylori antigens** in human faeces specimens to aid in the diagnosis of H. pylori infection.*



1. What is HELICOBACTER PYLORI?

Helicobacter pylori is a bacterium that can inhabit various areas of the stomach and duodenum. It is strongly linked to the development of duodenal and gastric ulcers and stomach cancer. Over 80% of individuals infected with the bacterium are asymptomatic despite having chronic gastritis.

More than 50% of the world's population harbor *H. pylori* in their upper gastrointestinal tract making it the most widespread infection in the world. *H. pylori* is contagious, although the exact route of transmission is not known. Person-to-person transmission by either the oral-oral or fecal-oral route is most likely.

2. What is H&R *H. pylori* test?

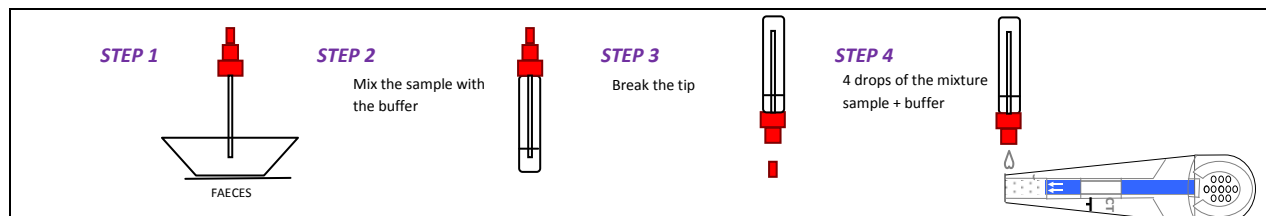
It is a rapid, one step test for **professional *in vitro* diagnostic use only**, for the qualitative detection of *Helicobacter pylori* (*H. pylori*) antigens in human faeces samples.

The main difference of the antigen against antibody is that the detection of specific IgAs and IgGs antibodies by using the rapid test method in patients infected by *H. pylori* is not reliable and it fails in the diagnosis because of the fact that **the antibodies don't distinguish between the active infection against the previous exposure to the microorganism** (the prevalence of these antibodies in adults is very high and the body takes about 3 to 6 months in eliminating them). Because of that, when the test is performed it could appear many false positives.

H&R *H. pylori* antigen test is a noninvasive method which provides **direct detection, and NOT ONLY PREVIOUS EXPOSURE, of an active infection and a monitoring result of eradication of the infection**. For that, the test can be used to detect repeat infections without any reduction in reliability. In addition, the test may be used within days of the initiation of anti-*H. pylori* therapy to confirm efficacy.

3. How is H&R *H. pylori* test performed?

- Collect sufficient quantity of faeces
- Unscrew the cap of the vial and introduce the stick into the faecal specimen to pick up enough sample.
- Introduce the stick with the sample into the vial and shake it in order to assure good sample dispersion.
- Break off the tip of the vial and open the poche to take the H&R *H. pylori* test device.
- Dispense 4 drops or 100 µL into the cassette and wait 10 minutes for the result.



3. Interpretation of results



4. Performance Data

- Sensitivity* is >99% compared to another commercial rapid test.
- Specificity* is >99% compared to another commercial rapid test.
- Accuracy*: the H&R *H. Pylori* test has been compared with different methods: cultures, Urea Breath Test and Urease Test, demonstrating an overall accuracy of >92%.
- Cross reactivity*: there is not cross reactivity with common intestinal pathogens, other organisms and substances occasionally present in feces.